



RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali

info@rwandafda.gov.rw

www.rwandafda.gov.rw

Kigali on; 10/12/2021
Ref N°: DIS/ 5050/FDA/2021

RMS Ltd (All Branches)
District Hospitals (All)
Referral Hospitals (All)
Central medical stores (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Public and private Health facilities (All)

Title: Recall of batch No. MTE20007 of ALBAMAS-400 (Albendazole tablets 400mg) manufactured by Mascot Health Series Pvt. Ltd, Uttarakhand / India.

Reference is made to the **Law N° 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13;

Reference is also made to Call for quarantine Ref. NO: DIS/3866/FDA/2021 issued by Rwanda FDA on October 27, 2021 for batch No. MTE20007 of ALBAMAS-400 (Albendazole tablets 400mg) manufactured by Mascot Health Series Pvt. Ltd, Uttarakhand / India;

Further reference is made to the deep investigation and laboratory quality control tests performed by Rwanda FDA on the concerned batch which confirmed the change of tablet colour and revealed most of tablets crumble when unpacked from blisters;

We regret to notify that the following batch were found with that quality issue and Rwanda FDA recalls it from the Rwandan market:

DESCRIPTION	BATCH	Mfg date	Exp date	Manufacturer
ALBAMAS-400 (Albendazole tablets 400mg)	MTE20007	05/2020	04/2023	Mascot Health Series Pvt. Ltd, Plot No. 78,80,Sec-6A, IIE, Sidcul, Haridwar-249403, Uttarakhand, India

(Signature)

Action to be taken

- Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, RMS Ltd branches, retailers, Public and Private Health Facilities to stop the distribution and dispensing of the above mentioned batch and return it to their supplier for proper disposal.
- The importers and Suppliers of the above incriminated batch of ALBAMAS-400 (Albendazole tablets 400mg) are requested to report to Rwanda FDA within 15 working days the quantities imported, quantities distributed, quantities returned and final stock on hand and apply for safe disposal.
- **Note:** For more information or to report any suspected poor quality products please call **0789193529** or **9707** or send email to: pv_sm@rwandafda.gov.rw

The authority takes into consideration every information from stakeholders to ensure safe and quality products.

Please find an attachment of the picture of the incriminated medicine being recalled

Sincerely,

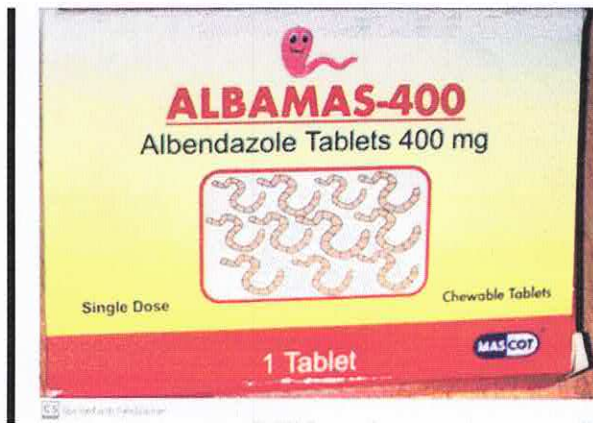
9/11/21
11/11/21

Dr. Emile BIENVENU
Director General



RWANDA FDA
Rwanda Food and Drugs Authority

Picture of recalled products



Composition :
Each uncoated chewable tablet contains:
Albendazole USP 400 mg
Excipients q.s

Dosage : As directed by the Physician.
Storage : Store at a temperature not exceeding 30°C.
Keep the medicine out of reach of children.

Mfg. Lic. No.: 68/UA/2009
Batch No.: MTE20007
Mfg. Date: 05/2020
Expiry Date: 04/2023



MAS-COT
Manufactured by:
Mascot Health Series Pvt. Ltd.
Plot No. 79.80, Sec-6A, IIE, Sidcul,
Haridwar-249403, Uttarakhand, INDIA.

Respect the Prescribed Dosage

